NATIONAL GUIDELINE CLEARINGHOUSE™ (NGC) GUIDELINE SYNTHESIS

SCREENING FOR BREAST CANCER

GUIDELINES BEING COMPARED

1. **American College of Physicians (ACP)**. Screening mammography for women 40 to 49 years of age: a clinical practice guideline from the American College of Physicians. Ann Intern Med 2007 Apr 3;146(7):511-5. [31 references]
2. **U.S. Preventive Services Task Force (USPSTF)**. 1) Screening for breast cancer: U.S. Preventive Services Task Force recommendation statement. 2) December 2009 addendum. Ann Intern Med 2009 Nov 17;151(10):716-726. [32 references]

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AREAS OF AGREEMENT AND DIFFERENCE

A direct comparison of the recommendations presented in the above guidelines for screening for breast cancer in asymptomatic women is provided in the tables below.

Areas of Agreement

Mammographic Screening In Women Aged 40 to 49 Years

Neither ACP nor USPSTF recommend routine screening mammography in women aged 40 to 49 years, with both groups recommending the decision to screen be an informed one made on a case-by-case basis. ACP recommends that clinicians: periodically (every 1 to 2 years) perform individualized assessment of risk for

breast cancer to help guide decisions about screening mammography; inform women about the potential benefits and harms of screening mammography; and base screening mammography decisions on benefits and harms of screening, as well as on a woman's preferences and breast cancer risk profile. USPSTF similarly recommends that the decision to start regular, biennial screening mammography before the age of 50 years be an individual one and take patient context into account, including the patient's values regarding specific benefits and harms.

With regard to recommended screening intervals in women in this age group who choose to undergo screening, USPSTF recommends biennial screening, noting that the evidence reviewed indicates that a large proportion of the benefit of screening mammography is maintained by biennial screening, and changing from annual to biennial screening is likely to reduce the harms of mammography screening by nearly half. ACP does not present recommendations regarding the frequency with which women in this age group should undergo screening mammography. They do, however, address screening intervals in the context of women in this age group with certain circumstances. They note that for women who do not wish to discuss the screening decision, screening mammography every 1 to 2 years is reasonable. They also note that if a woman decides to forgo mammography, clinicians should readdress the decision to have screening every 1 to 2 years.

Areas of Difference

Mammographic Screening In Women Older Than 49 Years of Age

USPSTF is the only group to provide screening recommendations for women older than 49 years of age. In women aged 50 to 74 years it recommends biennial screening mammography. For women 75 years or older, it concludes that the current evidence is insufficient to assess the additional benefits and harms of screening mammography, citing overdiagnosis and unnecessary earlier treatment as important potential harms of screening women in this age group.

Digital Mammography and Magnetic Resonance Imaging (MRI)

USPSTF is the only group to address screening using digital mammography and MRI, and concludes that the current evidence is insufficient to assess the additional benefits and harms of using either tool instead of film mammography as a screening modality for breast cancer.

Clinical Breast Examination (CBE) and Breast Self-Examination (BSE)

USPSTF is the only group to address CBE and BSE. It recommends against teaching BSE and concludes that the current evidence is insufficient to assess the additional benefits and harms of CBE beyond screening mammography in women 40 years or older.

ACP (2007)	**Recommendation 1**: *In women 40 to 49 years of age, clinicians should periodically perform individualized assessment of risk for breast cancer to help guide decisions about screening mammography*. A careful assessment of a woman's risk for breast cancer is important. Risk assessments should be updated periodically, particularly in women whose family history changes (for example, a relative receives a diagnosis of breast or ovarian cancer) and in women who choose not to have regular screening mammography. Although no evidence supports specific intervals, we encourage clinicians to update the woman's risk assessment every 1 to 2 years. Factors that increase the risk for breast cancer include older age, family history of breast cancer, older age at the time of first birth, younger age at menarche, and history of breast biopsy. Women 40 to 49 years of age who have any of the following risk factors have a higher risk for breast cancer than the average 50-year-old woman: two first-degree relatives with breast cancer; two previous breast biopsies; one first-degree relative with breast cancer and one previous breast biopsy; previous diagnosis of breast cancer, DCIS, or atypical hyperplasia; previous chest irradiation; or BRCA1 or BRCA2 mutation. **NGC Note**: Refer to the original guideline document for further discussion of risk assessment. **Recommendation 2**: *Clinicians should inform women 40 to 49 years of age about the potential benefits and harms of screening mammography*. Screening mammography for women 40 to 49 years of age is associated with both benefits and potential harms. The most important benefit of screening mammography every 1 to 2 years in women 40 to 49 years of age is a potential decrease in breast cancer mortality. Potential risks of mammography include false-positive results, diagnosis and treatment for cancer that would not have become clinically evident during the patient's lifetime, radiation exposure, false reassurance, and procedure-associated pain. False-positive mammography can lead to increased anxiety and to feelings of increased susceptibility to breast cancer, but most studies found that anxiety resolved quickly after the evaluation. **Recommendation 3**: *For women 40 to 49 years of age, clinicians*

should base screening mammography decisions on benefits and harms of screening, as well as on a woman's preferences and breast cancer risk profile.

Because the evidence shows variation in risk for breast cancer and benefits and harms of screening mammography based on an individual woman's risk profile, a personalized screening strategy based on a discussion of the benefits and potential harms of screening and an understanding of a woman's preferences will help identify those who will most benefit from screening mammography. For many women, the potential reduction in breast cancer mortality rate associated with screening mammography will outweigh other considerations. For women who do not wish to discuss the screening decision, screening mammography every 1 to 2 years in women 40 to 49 years of age is reasonable.

Important factors in the decision to undergo screening mammography are women's preferences for screening and the associated outcomes. Concerns about risks for breast cancer or its effect on quality of life will vary greatly among women. Some women may also be particularly concerned about the potential harms of screening mammography, such as false-positive mammograms and the resulting diagnostic work-up. When feasible, clinicians should explore women's concerns about breast cancer and screening mammography to help guide decision making about mammography.

The relative balance of benefits and harms depends on women's concerns and preferences and on their risk for breast cancer. Clinicians should help women to judge the balance of benefits and harms from screening mammography. Women who are at greater-than-average absolute risk for breast cancer and who are concerned that breast cancer would have a severely adverse effect on quality of life may derive a greater-than-average benefit from screening mammography. Women who are at substantially lower-than-average risk for breast cancer or who are concerned about potential risks of mammography may derive a less-than-average benefit from screening mammography.

If a woman decides to forgo mammography, clinicians should readdress the decision to have screening every 1 to 2 years.

Recommendation 4: *ACP recommends further research on the net benefits and harms of breast cancer screening modalities for women 40 to 49 years of age*.

Methodological issues associated with existing breast cancer screening trials, such as compliance with screening, lack of statistical power, and inadequate information about inclusion or exclusion criteria and study population, heighten the need for high-quality trials to confirm the effectiveness of screening

	mammography in women in this age group. Furthermore, harms of screening in this age group, such as pain, radiation exposure, and adverse outcomes related to false-positive results, should also be studied.
USPSTF (2009)	The decision to start regular, biennial screening mammography before the age of 50 years should be an individual one and take patient context into account, including the patient's values regarding specific benefits and harms. **This is a C recommendation**. **Clinical Considerations** **Patient Population Under Consideration** This recommendation statement applies to women 40 years or older who are not at increased risk for breast cancer by virtue of a known underlying genetic mutation or a history of chest radiation.
MAMMOGRAPHIC SCREENING IN WOMEN OLDER THAN 49 YEARS OF AGE Abbreviations Back to TOC	
ACP (2007)	No recommendations offered.
USPSTF (2009)	The USPSTF recommends biennial screening mammography for women aged 50 to 74 years. **This is a B recommendation**. The USPSTF concludes that the current evidence is insufficient to assess the additional benefits and harms of screening mammography in women 75 years or older. **This is an I statement**. **Clinical Considerations** **Patient Population Under Consideration** This recommendation statement applies to women 40 years or older who are not at increased risk for breast cancer by virtue of a known underlying genetic mutation or a history of chest radiation. **Screening Intervals** In trials that demonstrated the effectiveness of mammography in decreasing breast cancer mortality, screening was performed every 12 to 33 months. The evidence reviewed by the USPSTF indicates that a large proportion of the benefit of screening mammography is maintained by biennial screening, and changing from annual to

	biennial screening is likely to reduce the harms of mammography screening by nearly half. At the same time, benefit may be reduced when extending the interval beyond 24 months; therefore the USPSTF recommends biennial screening. **Considerations for Practice Regarding I Statements** *Screening Mammography in Women 75 Years or Older* Potential Preventable Burden. No women 75 years or older have been included in the multiple randomized clinical trials of breast cancer screening. Breast cancer is a leading cause of death in older women, which might suggest that the benefits of screening could be important at this age. However, 3 facts suggest that benefits from screening would probably be smaller for this age group than for women aged 60 to 69 years and probably decrease with increasing age: 1) the benefits of screening only occur several years after the actual screening test, whereas the percentage of women who survive long enough to benefit decreases with age; 2) a higher percentage of the type of breast cancer detected in this age group is the more easily treated estrogen receptor-positive type; and 3) women of this age are at much greater risk for dying of other conditions that would not be affected by breast cancer screening. Potential Harms. Screening detects not only cancer that could lead to a woman's death but also cancer that will not shorten a woman's life. Women cannot benefit from—but can be harmed by—the discovery and treatment of this second type of cancer, which includes both cancer that might someday become clinically apparent and cancer that never will. Detection of cancer that would never have become clinically apparent is called overdiagnosis, and it is usually followed by overtreatment. Because of a shortened life span among women 75 years or older, the probability of overdiagnosis and unnecessary earlier treatment increases dramatically after about age 70 or 75 years. Overdiagnosis and unnecessary earlier treatment are important potential harms from screening women in this age group. Current Practice. Studies show that many women 75 years or older are currently being screened.
DIGITAL MAMMOGRAPHY AND MRI **Abbreviations** **Back to TOC**	
ACP (2007)	No recommendations offered.
USPSTF (2009)	The USPSTF concludes that the current evidence is insufficient to assess the additional benefits and harms of either digital

mammography or MRI instead of film mammography as screening modalities for breast cancer. **This is an I statement**.

Considerations for Practice Regarding I Statements

Digital Mammography

Potential Preventable Burden. Digital mammography detects some cases of cancer not identified by film mammography; film mammography detects some cases of cancer not identified by digital mammography. Overall detection is similar for many women. For women who are younger than 50 years or have dense breast tissue, overall detection is somewhat higher with digital mammography. It is not clear whether this additional detection would lead to reduced mortality from breast cancer.

Potential Harms. The possibility of false-positive test results is similar for film and digital mammography. It is uncertain whether overdiagnosis occurs more with digital mammography than with film mammography.

Costs. Digital mammography is more expensive than film mammography.

Current Practice. Some clinical practices are now switching their mammography equipment from film to digital. This may curtail the availability of film mammography in some areas.

Magnetic Resonance Imaging

Potential Preventable Burden. Studies of the use of contrast-enhanced MRI for breast cancer screening have been conducted only in very high-risk populations. In these studies, MRI detected more cases of cancer than did mammography. It is unknown whether detecting these additional cases of cancer would lead to reduced breast cancer mortality.

Potential Harms. Contrast-enhanced MRI requires the injection of contrast material. Studies of MRI screening have shown that MRI yields many more false-positive results than does mammography. Magnetic resonance imaging has the potential to be associated with a greater degree of overdiagnosis than mammography.

Costs. Magnetic resonance imaging is much more expensive than either film or digital mammography.

Current Practice. Magnetic resonance imaging is not currently used for screening women at average risk for breast cancer.

(BSE) Abbreviations Back to TOC	
ACP (2007)	No recommendations offered.
USPSTF (2009)	Adequate evidence suggests that teaching BSE does not reduce breast cancer mortality. There is adequate evidence that teaching BSE is associated with harms that are at least small. For the teaching of BSE, there is moderate certainty that the harms outweigh the benefits. The USPSTF recommends against teaching BSE. **This is a D recommendation**. The USPSTF concludes that the current evidence is insufficient to assess the additional benefits and harms of CBE beyond screening mammography in women 40 years or older. **This is an I statement**. **Considerations for Practice Regarding I Statements** *Clinical Breast Examination* Potential Preventable Burden. The evidence for CBE, although indirect, suggests that CBE may detect a substantial proportion of cases of cancer if it is the only screening test available. In parts of the world where mammography is infeasible or unavailable (such as India), CBE is being investigated in this way. Potential Harms. The potential harms of CBE are thought to be small but include false-positive test results, which lead to anxiety and breast cancer worry, as well as repeated visits and unwarranted imaging and biopsies. Costs. The principal cost of CBE is the opportunity cost incurred by clinicians in the patient encounter. Current Practice. Surveys suggest that the CBE technique used in the United States currently lacks a standard approach and reporting standards. Clinicians who are committed to spending the time on CBE would benefit their patients by considering the evidence in favor of a structured, standardized examination.

STRENGTH OF EVIDENCE AND RECOMMENDATION GRADING SCHEMES Abbreviations Back to TOC

ACP (2007)	**Levels of Evidence** **Therapy or Prevention, Etiology or Harm** 1a: Systematic review of randomized controlled trials (RCTs) 1b: Individual RCT (with narrow confidence interval) 1c: All or none 2a: Systematic review of cohort studies 2b: Individual cohort study (including low quality RCT; e.g., <80% follow-up) 2c: "Outcomes" research; ecological studies 3a: Systematic review of case-control studies 3b: Individual case-control study 4: Case-series (and poor quality cohort and case-control studies) 5: Expert opinion without explicit critical appraisal or based on physiology, bench research or "first principles" **Prognosis** 1a: Systematic review of inception cohort studies 1b: Individual inception cohort study with >80% follow-up 1c: All or no case-series 2a: Systematic review of either retrospective cohort studies or untreated control groups in RCTs 2b: Retrospective cohort study or follow-up of untreated control patients in an RCT 2c: "Outcomes" research 4: Case-series (and poor quality prognostic cohort studies) 5: Expert opinion without explicit critical appraisal, or based on physiology, bench research or "first principles"

Symptom Prevalence Study

1a: Systematic review of prospective cohort studies

1b: Prospective cohort study with > 80% follow-up

1c: All or no case-series

2a: Systematic review of 2b and better studies

2b: Retrospective cohort study or poor follow-up

2c: Ecological studies

3a Systematic review of 3b and better studies

3b: Non-consecutive cohort study, or very limited study population

4: Case-series or superseded reference standards

5: Expert opinion without explicit critical appraisal or based on physiology, bench research or "first principles"

USPSTF (2009)

What the United States Preventive Services Task Force (USPSTF) Grades Mean and Suggestions for Practice

Grade	Grade Definitions	Suggestions for Practice
A	The USPSTF recommends the service. There is high certainty that the net benefit is substantial.	Offer or provide this service.
B	The USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial.	Offer or provide this service.
C	The USPSTF recommends against routinely providing the service. There may be considerations that support providing the service in an individual patient. There is moderate or high certainty that the net benefit is small.	Offer or provide this service only if other considerations support offering or providing the service in an individual patient.
D	The USPSTF recommends against the service. There is moderate or high certainty	Discourage the use of this service.

	that the service has no net benefit or that the harms outweigh the benefits.	
I Statement	The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.	Read "Clinical Considerations" section of USPSTF Recommendation Statement (see "Major Recommendations" field). If this service is offered, patients should understand the uncertainty about the balance of benefits and harms.

USPSTF Levels of Certainty Regarding Net Benefit

Definition: The U.S. Preventive Services Task Force defines certainty as "likelihood that the USPSTF assessment of the net benefit of a preventive service is correct." The net benefit is defined as benefit minus harm of the preventive service as implemented in a general, primary care population. The USPSTF assigns a certainty level based on the nature of the overall evidence available to assess the net benefit of a preventive service.

Level of Certainty	Description
High	The available evidence usually includes consistent results from well-designed, well-conducted studies in representative primary care populations. These studies assess the effects of the preventive service on health outcomes. This conclusion is therefore unlikely to be strongly affected by the results of future studies.
Moderate	The available evidence is sufficient to determine the effects of the preventive service on health outcomes, but confidence in the estimate is constrained by factors such as: • The number, size, or quality of individual studies • Inconsistency of findings across individual studies • Limited generalizability of findings to routine primary care practice • Lack of coherence in the chain of evidence As more information becomes available, the magnitude or direction of the observed effect could change, and this change may be large enough to alter the conclusion.
Low	The available evidence is insufficient to assess effects on health outcomes. Evidence is insufficient because of: • The limited number or size of studies • Important flaws in study design or methods

	• Inconsistency of findings across individual studies • Gaps in the chain of evidence • Findings not generalizable to routine primary care practice • A lack of information on important health outcomes More information may allow an estimation of effects on health outcomes.

COMPARISON OF METHODOLOGY ***Click on the links below for details of guideline development methodology***	
ACP **(2007)**	**USPSTF** **(2009)**
A systematic evidence review update was prepared by the Oregon Evidence-Based Practice Center (EPC) for use by the USPSTF in the development of its guideline. In addition, six modeling studies were conducted by the Breast Cancer Working Group of the Cancer Intervention and Surveillance Modeling Network (CISNET) for use by the USPSTF. To collect and select the evidence both groups performed searches of electronic databases and hand searches of published literature (primary sources); USPSTF also performed hand searches of published literature (secondary sources). Methods used to assess the quality and strength of the evidence differ, with ACP using weighting according to a rating scheme (scheme provided) and USPSTF employing expert consensus. With regard to analysis of the evidence, both groups performed a review of published meta-analyses as well as a systematic review. The USPSTF systematic review incorporated evidence tables. USPSTF differs from ACP in that it also performed a meta-analysis of randomized controls trials. Both groups used expert consensus to formulate the recommendations; USPSTF also employed balance sheets. While USPSTF provides a description of the recommendation formulation process, ACP does not. An additional difference is that USPSTF grades the strength of its recommendations according to a rating scheme; ACP does not. With regard to cost concerns, for context purposes the USPSTF reviewed studies focused on costs and cost savings of screening, comparisons of screening strategies or programs, and costs for older women. However, the USPSTF did not use cost as a factor when making its recommendations. ACP did not perform a formal cost analysis and did not review published cost analyses. Both internal and external peer review was performed as methods of guideline validation for both groups; USPSTF also compared its guideline with those of other groups.	

SOURCE(S) OF FUNDING Abbreviations Back to TOC	
ACP (2007)	American College of Physicians
USPSTF (2009)	United States Government

BENEFITS AND HARMS Abbreviations Back to TOC	
Benefits	
ACP (2007)	Screening mammography likely reduces breast cancer mortality in women 40 to 49 years of age modestly. However, compared to women over 50, the reduction in mortality is smaller and subject to greater uncertainty about the exact reduction in risk and comes with the risk of potential harms.
USPSTF (2009)	**Benefits of Detection and Early Intervention** • There is convincing evidence that screening with film mammography reduces breast cancer mortality, with a greater absolute reduction for women aged 50 to 74 years than for women aged 40 to 49 years. The strongest evidence for the greatest benefit is among women aged 60 to 69 years. • Among women 75 years or older, evidence of benefits of mammography is lacking. • Adequate evidence suggests that teaching BSE does not reduce breast cancer mortality. • The evidence for additional effects of CBE beyond mammography on breast cancer mortality is inadequate. • The evidence for benefits of digital mammography and MRI of the breast, as a substitute for film mammography, is also lacking.
Harms	
ACP (2007)	• Risks of mammography include false-positive results, diagnosis of cancer that would not have become clinically evident during the patient's lifetime, radiation exposure, false reassurance, and procedure-associated pain. • Women 40 to 49 years of age may have a higher risk for a false-

	positive result, and false-positive rates vary widely among several studies.
USPSTF (2009)	**Harms of Detection and Early Intervention** • The harms resulting from screening for breast cancer include psychological harms, unnecessary imaging tests and biopsies in women without cancer, and inconvenience due to false-positive screening results. Furthermore, one must also consider the harms associated with treatment of cancer that would not become clinically apparent during a woman's lifetime (overdiagnosis), as well as the harms of unnecessary earlier treatment of breast cancer that would have become clinically apparent but would not have shortened a woman's life. Radiation exposure (from radiologic tests), although a minor concern, is also a consideration. • Adequate evidence suggests that the overall harms associated with mammography are moderate for every age group considered, although the main components of the harms shift over time. Although false-positive test results, overdiagnosis, and unnecessary earlier treatment are problems for all age groups, false-positive results are more common for women aged 40 to 49 years, whereas overdiagnosis is a greater concern for women in the older age groups. • There is adequate evidence that teaching BSE is associated with harms that are at least small. There is inadequate evidence concerning harms of CBE.

Abbreviations
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ACP, American College of Physicians

BSE, breast self-examination

CBE, clinical breast examination

DCIS, ductal carcinoma in situ

MRI, magnetic resonance imaging

USPSTF, U.S. Preventive Services Task Force

This Guideline Synthesis was prepared by ECRI on December 28, 1998. It was reviewed and verified by the guideline developers as of February 19, 1999. This

Synthesis was subsequently modified by ECRI in 2001, 2002, 2003, 2004, and 2005. The most current version of this Synthesis incorporates the 2004 UMHS recommendations. This synthesis was verified by UMHS on November 3, 2005. This Synthesis was updated by ECRI on August 8, 2006 and on December 14, 2006 following the withdrawal of the Kaiser Permanente Southern California guideline, and the Brigham and Women's and Canadian Task Force guidelines respectively from the NGC Web site. This synthesis was revised on November 27, 2007 to remove recommendations from USPSTF. This synthesis was revised on January 28, 2008 to add ACP recommendations. The information was verified by ACP on February 4, 2008. This synthesis was revised on May 2, 2008 to incorporate the 2007 ACS addendum. This Synthesis was revised in October 2008 to remove outdated ACOG recommendations and again in December 2009 to add USPSTF recommendations and to remove ACS and UMHS recommendations. The information was verified by USPSTF on January 29, 2010.

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